



Under the Freedom of Information Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

PTO/SB/08a (05-07)  
Approved for use through 09/30/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** ( Not for submission under 37 CFR 1.99)

Application Number		10611584
Filing Date		2003-07-01
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name	SASAN, ARADHANA	
Attorney Docket Number	065478-0219	

## **U.S.PATENTS**

Examiner Initial*	Cite No	Patent Number	Kind Code1	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	4554276		2007-10-17	LaMattina	
	2	4676984		1987-06-30	Wu et al.	
	3	4757060		1988-07-12	Lukacsko et al.	
	4	4766117		1988-08-23	Crawford et al.	
	5	4853230		1988-11-22	Lovgren et al.	
	6	5037815		1991-08-06	Lukacsko et al.	
	7	5071643		1991-12-10	Yu et al.	
	8	5204118		1993-04-20	Goldman et al.	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10611584
Filing Date	2003-07-01
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	SASAN, ARADHANA
Attorney Docket Number	065478-0219

9	5417980	1995-05-23	Goldman et al.	
10	5629013	1997-05-13	Upson et al.	
11	5753265	1998-05-19	Bergstrand et al.	
12	5763422	1998-06-09	Lichtenberger et al.	
13	5817338	1998-10-06	Bergstrand et al.	
14	5955451	1999-09-21	Lichtenberger et al.	
15	5972389	1999-10-26	Shell et al.	
16	6015801	2000-01-18	Daifotis et al.	
17	6024222	2000-02-15	Frberg et al.	
18	6090827	2000-07-18	Erickson et al.	
19	6160020	2000-12-12	Ohannesian et al.	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10611584
Filing Date	2003-07-01
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	SASAN, ARADHANA
Attorney Docket Number	065478-0219

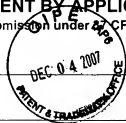
20	6183779	2001-02-06	Ouali et al.	
21	6365184	2002-04-02	Depui et al.	
22	6392525	2002-05-21	Kato et al.	
23	6544556	2003-04-08	Chen et al.	
24	6613354	2003-09-02	Depui et al.	
25	6759935	2004-07-06	Moro et al.	
26	4786505	1998-11-22	Lovgren et al.	
27	5464632	1995-11-07	Cousin et al.	
28	5731002	1998-03-24	Olovson et al.	
29	6132770	2000-10-17	Lundberg	
30	6299904	2001-10-09	Shimizu et al.	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10611584
Filing Date	2003-07-01
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	SASAN, ARADHANA
Attorney Docket Number	065478-0219

31	6328994	2001-12-11	Shimizu et al.	
32	6489346	2002-12-02	Phillips et al.	
33	6183776	2001-02-06	Depui et al.	
34	5840737	1998-11-24	Phillips et al.	
35	5589491	1996-12-31	Nakanishi et al.	
36	6096340	2000-08-10	Chih-Ming Chen et al.	
37	5750104	1998-05-12	Sipos	
38	6328993	2001-12-11	Linder et al.	
39	5312818	1994-05-17	Rubin et al.	
40	6013281	2001-01-11	Lundberg	
41	6258845	2001-07-01	Gerner	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
(Not for submission under 37 CFR 1.99)



Application Number		10611584
Filing Date		2003-07-01
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name	SASAN, ARADHANA	
Attorney Docket Number	065478-0219	

**U.S. PATENTS**

Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

**U.S. PATENT APPLICATION PUBLICATIONS**

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

**FOREIGN PATENT DOCUMENTS**

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	58056664	JP		1983-04-04			<input type="checkbox"/>
	2	01/51050	WO		2001-07-19	University of Missouri		<input type="checkbox"/>
	3	94/02140	WO		2000-05-11	Yositomi Pharmaceutical Ind. Ltd.		<input type="checkbox"/>

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)			Application Number	10611584
			Filing Date	2003-07-01
			First Named Inventor	Taneja, Rajneesh
			Art Unit	1615
			Examiner Name	SASAN, ARADHANA
			Attorney Docket Number	065478-0219

4	97/25030	WO		1997-07-17	Astra Aktiebolag	<input type="checkbox"/>
---	----------	----	--	------------	------------------	--------------------------

If you wish to add additional Foreign Patent Document citation information please click the Add button

#### NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1		<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

#### EXAMINER SIGNATURE

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number	10611584
	Filing Date	2003-07-01
	First Named Inventor	Taneja, Rajneesh
	Art Unit	1615
	Examiner Name	SASAN, ARADHANA
Attorney Docket Number	065478-0219	

42	5952021		1999-09-14	Santus	
43	6800307		2004-10-05	Matthews et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

#### U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20020051814		2002-05-02	Chen	
	2	20020051814		2002-05-02	Chen	
	3	20020192299		2002-12-19	Taneja et al.	
	4	20020045646		2002-04-18	Phillips	

If you wish to add additional U.S. Published Application citation information please click the Add button.

#### FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> i	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	85/03443	WO		1985-08-15	Sunshine et al.		<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		10611584
Filing Date		2003-07-01
First Named Inventor	Taneja, Rajneesh	
Art Unit	1615	
Examiner Name	SASAN, ARADHANA	
Attorney Docket Number	065478-0219	

2	93/12517	WO		1993-06-24	Fujushita et al.		<input type="checkbox"/>
3	95/32957	WO		1995-12-07	Von Unge		<input type="checkbox"/>
4	96/01623	WO		1996-01-25	Bergstrand et al.		<input type="checkbox"/>
5	96/01625	WO		1996-01-25	Bergstrand et al.		<input type="checkbox"/>
6	96/07421	WO		1996-03-14	Satoh		<input type="checkbox"/>
7	96/22780	WO		1996-08-01	Lichtenberger et al.		<input type="checkbox"/>
8	96/24375	WO		1996-08-15	Depui et al.		<input type="checkbox"/>
9	97/25064	WO		1997-07-17	Depui et al.		<input type="checkbox"/>
10	97/25066	WO		1997-07-17	Depui et al.		<input type="checkbox"/>
11	98/11879	WO		1998-03-26	Shell et al.		<input type="checkbox"/>
12	98/13073	WO		1998-04-02	Lichtenberger et al.		<input type="checkbox"/>



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10611584
Filing Date	2003-07-01
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	SASAN, ARADHANA
Attorney Docket Number	065478-0219

13	98/50033	WO		1998-11-12	Lundy et al.		<input type="checkbox"/>
14	99/01000	WO		1999-01-07	Jokinen		<input type="checkbox"/>
15	99/12524	WO		1999-03-18	Skinhoh et al.		<input type="checkbox"/>
16	99/36060	WO		1999-07-22	Wilson et al.		<input type="checkbox"/>
17	99/39700	WO		1999-08-12	Esposito et al.		<input type="checkbox"/>
18	99/59612	WO		1999-11-25	Gevas et al.		<input type="checkbox"/>
19	99/66919	WO		1999-12-29	Ohannesian et al.		<input type="checkbox"/>
20	00/16750	WO		2000-03-30	Pettersson et al.		<input type="checkbox"/>
21	00/27366	WO		2000-05-18	Bergstrand et al.		<input type="checkbox"/>
22	00/50007	WO		2000-08-31	Patel et al.		<input type="checkbox"/>
23	00/50037	WO		2000-08-31	Garvey et al.		<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10611584
Filing Date	2003-07-01
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	SASAN, ARADHANA
Attorney Docket Number	065478-0219

	24	00/51583	WO		2000-09-08	Rubin et al.		<input type="checkbox"/>
	25	00/69438	WO		2000-11-23	Rumsey et al.		<input type="checkbox"/>
	26	00/71122	WO		2000-11-30	Malcolm		<input type="checkbox"/>
	27	00/72838	WO		2000-12-07	Eek et al.		<input type="checkbox"/>
	28	01/03707	WO		2000-12-14	Mandel et al.		<input type="checkbox"/>
	29	01/13897	WO		2001-01-18	Wilson et al.		<input type="checkbox"/>
	30	01/16750	WO		2001-03-08	West et al.		<input type="checkbox"/>
	31	01/19330	WO		2001-03-22	DeBony et al.		<input type="checkbox"/>
	32	01/37808	WO		2001-05-31	Patel et al.		<input type="checkbox"/>
	33	4432262	DE		1995-07-20	Denecke		<input type="checkbox"/>
	34	0426479	EP		1994-02-16	Goldman et al.		<input type="checkbox"/>

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)			Application Number	10611584
			Filing Date	2003-07-01
			First Named Inventor	Taneja, Rajneesh
			Art Unit	1615
			Examiner Name	SASAN, ARADHANA
			Attorney Docket Number	065478-0219

	35	2105193	GB		1983-03-23	Marriott et al.		<input type="checkbox"/>
	36	2105588	GB		1983-03-30	Brittain et al.		<input type="checkbox"/>
	37	2120938	GB		1983-12-14	Ezer et al.		<input type="checkbox"/>
	38	P2000-26296	JP					<input type="checkbox"/>
	39	00/51584	WO		2000-09-08	Rubin et al.		<input type="checkbox"/>
	40	94/25070	WO		1994-11-10	Astra Aktiebolag		<input type="checkbox"/>
	41	00/74654	WO		2000-05-31	Byk Gulden		<input type="checkbox"/>
	42	02/45692	WO		2001-05-12	Byk Gulden		<input type="checkbox"/>
	43	02/22108	WO		2002-03-21	Chih Ming Chen		<input type="checkbox"/>
	44	19925710	DE		2000-12-14	Gulden et al.		<input type="checkbox"/>
	45	0547000	EP		1993-06-16			<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10611584
Filing Date	2003-07-01
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	SASAN, ARADHANA
Attorney Docket Number	065478-0219

46	01/51050	WO		2001-07-19	Univ. of Missouri		<input type="checkbox"/>
47	00/26185	WO		2000-05-11			<input type="checkbox"/>
48	747293	GB		1956-04-01	Abbott Labs		<input type="checkbox"/>
49	0264259	EP		1988-04-01	Kouchiwa et al.		<input type="checkbox"/>
50	745493	GB		2007-10-18	MacLeans Ltd.		<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	File history of EP Patent Application No: 0426479B1 including the following: European patent application as filed, European search report of February 22, 1991, First Office Action of August 10, 1992 and applicant's reply of December 3, 1992, Communication under Rule 51(4) EPC of February 17, 1993, Applicant's letter of July 30, 1993, Decision to grant a European patent pursuant to Article 97(2) EPC of January 6, 1994 including the non-patent references cited, Communication of notices of opposition (Rule 57(1) EPC) of December 22, 1994, Communication of	<input type="checkbox"/>
	2	Search Results for NSAIDS in Combination with Proton Pump Inhibitors-performed in 2001	<input type="checkbox"/>
	3	Search Results for Proton Pump Inhibitors and NSAIDS co-administered - performed in 2001	<input type="checkbox"/>
	4	WILSON INGALL ET AL.: "Management of gastroduodenal ulcers and gastrointestinal symptoms associated with nonsteroidal anti-inflammatory drug therapy: A summary of four comparative trials with omeprazole, ranitidine, misoprostol and placebo" Current Therapeutic Research, December, 2001, pp. 835-850, Vol. 62, No. 12	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT****( Not for submission under 37 CFR 1.99)**

Application Number	10611584
Filing Date	2003-07-01
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	SASAN, ARADHANA
Attorney Docket Number	065478-0219

5	ROTE LISTE SERVICE: "Rote Liste 2000," 2000, Rote Liste Service, GmbH, Frankfurt, DE A.M. XP002222579	<input type="checkbox"/>
6	ROTE LISTE SERVICE: "Rote Liste 2000," 2000, Rote Liste Service, GmbH, Frankfurt, DE A.M. XP002222580	<input type="checkbox"/>
7	PHILLIPS, JEFFREY O. ET AL., "A Prospective Study of Simplified Omeprazole Suspension for the Prophylaxis of Stree-Related Mucosal Damage," Crit. Care Med., 1996, pp. 1793-1800, Vol. 24 No. 11	<input type="checkbox"/>
8	LANDES, B. DELHOTAL ET AL., "Clinical Pharmacokinetics of Lansoprazole," Clin. Pharmacokinet., 1995, pp. 458-470, Vol. 28, No. 6	<input type="checkbox"/>
9	SHARMA, V.K. ET AL., "The Effects on Intragastric Acidity of Per-Gastrostomy Administration of an Alkaline Suspension of Omeprazole," Aliment. Pharmacol. Ther., 1999, pp. 1091-1095, Vol. 13	<input type="checkbox"/>
10	SHARMA, V.K. ET AL., "Oral pharmacokinetics of Omeprazole and Lansoprazole After Single and Repeated Doses as Intact Capsules or as Suspensions in Bicarbonate," Aliment. Pharmacol. Ther., 2000, pp. 887-892, Vol. 14, No. 7	<input type="checkbox"/>
11	SHARMA, V.K. ET AL., "Simplified Lansoprazole Suspension - A Liquid Formulation of Lansoprazole Effectively Suppresses Intragastric Acidity When Administered Through a Gastrostomy" Am. J. Gastroenterology, August 1999, pp. 1813-1817, Vol. 94, No. 7	<input type="checkbox"/>
12	LEWIS, ET AL., "The Physical and Chemical Stability of Suspensions of Sustained-Release Diclofenac Microspheres" J. Microencapsulation, Sept. 1, 1998, pp. 555-567 Vol. 15, No. 5	<input type="checkbox"/>
13	SHARMA, V.K. ET AL., "The Pharmacodynamics of Lansoprazole Administered via Gastrostomy as Intact, Non- Encapsulated Granules," Aliment. Pharmacol. Ther., 1998, pp. 1171-1174, Vol. 12,	<input type="checkbox"/>
14	SHARMA, V.K., "Comparison of 24-hour Intragastric pH Using Four Liquid Formulations of Lansoprazole and Omeprazole," Am. J. Health Syst. Pharm., Dec. 1, 1999, Vol. 56 Supp. 4.	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10611584
Filing Date	2003-07-01
First Named Inventor	Taneja, Rajneesh
Art Unit	1615
Examiner Name	SASAN, ARADHANA
Attorney Docket Number	065478-0219

**EXAMINER SIGNATURE**

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.